Remarks

The Amendments

Claim 7 has been amended to recite that the diagnostic agent for Rothmund-Thomson syndrome "comprises a preparation of antibodies which specifically bind to RecQ4 helicase as shown in SEQ ID NO:4" in place of "contains as the effective ingredient an antibody which is capable of binding to RecQ4 helicase as shown in SEQ ID NO:4." The specification supports the amendment that the diagnostic agent comprises a preparation of antibodies at page 17, lines 32-34: "Antibodies binding to RecQ4 helicase can be prepared by a method known to those skilled in the art." The specification supports the amendment that the antibody preparation specifically binds to RecQ4 helicase at page 40, lines 5-7: "Based on the above-described results, it was confirmed that the monoclonal antibody K6314 specifically recognizes the RecQ4 helicase protein." Thus, these amendments introduce no new matter.

These amendments do not require any additional search. These amendments were not earlier made because they are a direct response to an anticipation rejection (over Fu *et al.*, see comments below) first raised by the Patent Office in the pending final Office Action. Applicants believe that the amendment places the claims in condition for allowance.

Applicants respectfully request entry of these amendments.

The Rejection of Claim 7 Under 35 U.S.C. § 102(e)

Claim 7 stands rejected under 35 U.S.C. § 102(e) as being anticipated by Fu *et al.* (U.S. Patent No. 6,090,620; "Fu"). Applicants respectfully traverse the rejection.

Claim 7 is directed to a diagnostic agent for Rothmund-Thomson syndrome. The agent

comprises a preparation of antibodies which specifically bind to RecQ4 helicase as shown in SEQ ID NO:4.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987). Fu does not anticipate claim 7 because Fu does not teach antibodies which specifically bind to RecQ4 helicase as shown in SEQ ID NO:4.

The Office Action asserts that Fu teaches an antibody that is capable of binding SEQ ID NO:4 because Fu teaches antibodies that bind to proteins and Fu teaches an amino acid sequence, SEQ ID NO:75, that shares regions of identity with applicants' amino acid sequence shown in SEQ ID NO:4. Final Office Action, page 2, last ¶. The Office Action states that because "it is well known in the art that the minimum requirement for an antibody epitope is 6 contiguous amino acids, in the absence of evidence to the contrary the antibody taught by Fu et al would be 'capable' of binding to RecQ4 as claimed." Final Office Action, sentence bridging pages 2 and 3.

The amino acid sequence taught by Fu, SEQ ID NO:75, shares several regions of identity SEQ ID NO:4 of the instant application. These regions of identity contain six or more amino acid residues. However, Fu does not teach antibodies that bind to a polypeptide having the amino acid sequence of SEQ ID NO:75.

Fu teaches antibodies that specifically bind to WRN protein or polypeptides derived from WRN protein. Fu teaches:

> Within other aspects of the present invention, antibodies are provided which specifically bind to an WRN protein or to unique

> peptides derived therefrom. As utilized herein, it should be understood that an antibody is specific for an WRN protein (or peptide) if it binds detectably, and with a K_d of 10^{-7} M or less (e.g., 10^{-8} M, 10^{-9} M, etc.), but does not bind detectably (or with an affinity of greater than 10^{-7} M, (e.g., 10^{-6} M, 10^{-5} M, etc.) to an unrelated helicase (e.g., the Bloom's syndrome gene supra).

Column 3, lines 8-16. SEQ ID NO:75, as taught by Fu, is *not* the amino acid sequence of a WRN protein or a polypeptide derived from a WRN protein. SEQ ID NO:75, as taught by Fu, is the amino acid sequence of an *E. coli* helicase. Fu teaches, "FIGS. 4A-4G are an alignment of the WRN gene product (SEQ ID No. 74) with known helicases from *S. pombe* (SEQ ID No. 76), *E. coli* (SEQ ID No. 75), human (SEQ ID No. 77) and Bloom's Syndrome gene 'BLM' (SEQ ID No. 78)." Column 4, lines 33-37. As the amino acid sequence of SEQ ID NO:75 is not the amino acid sequence of a WRN protein, Fu does not teach antibodies to a polypeptide having the amino acid sequence of SEQ ID NO:75.

Nonetheless, Fu does not teach each and every element recited in amended claim 7. Claim 7 is directed to a diagnostic agent comprising an antibody preparation. The antibody preparation "specifically bind[s] to RecQ4 helicase as shown in SEQ ID NO:4." Fu does not teach antibody preparations that specifically bind to RecQ4 helicase as shown in SEQ ID NO:4. Fu teaches antibodies specific to WRN protein. See Fu at column 3, lines 8-16, quoted above. In fact, Fu teaches that his antibodies specific for an WRN protein do not bind detectably to an unrelated helicase, *e.g.*, the RecQ4 helicase of SEQ ID NO:4. Fu teaches that "an antibody is specific for an WRN protein (or peptide) if it binds detectably, and with a K_d of 10^{-7} M or less (e.g., 10^{-8} M, 10^{-9} M, etc.), but does not bind detectably (or with an affinity of greater than 10^{-7} M, (e.g., 10^{-6} M, 10^{-5} M, etc.) to an unrelated helicase (e.g., the Bloom's syndrome gene supra)." Column 3, lines 11-16. Thus, claim 7 recites a diagnostic agent which includes antibodies

specific for SEQ ID NO:4 while Fu teaches antibodies specific for an unrelated helicase, *i.e.*, WRN protein. Fu, therefore, does not teach each and every element as recited in claim 7 and Fu does not anticipate claim 7.

Applicants respectfully request withdrawal of this rejection.

Respectfully submitted,

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